Electronic Version
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Claims

[c1] A method for clinical trial data management comprising:
entering clinical trial data directly by an examining clinician using a remote computing device;
determining whether the remote computing device is communicatively coupled to a central server;
transmitting the clinical trial data from the remote computing device to the central server in response to a determination that the remote computing device is communicatively coupled to the central server; and
storing the data in a secure store within the remote computing device in response to a determination that the remote computing device is not communicatively coupled to the central server.

[c2] The method of claim 1 wherein the step of entering includes:
digitizing an image of hand drawn information entered by the clinician on the remote computing device.

[c3] The method of claim 1 wherein the step of entering includes:
entering fields of the clinical trial data in response to an electronic form presented to the clinician on the remote

computing device.

[c4] The method of claim 3 wherein the step of entering form data further includes:
validating the entered clinical trial data within the remote computing device.

[c5] The method of claim 4 wherein the electronic form is defined as an XML schema and wherein the step of validating comprises validating the entered clinical trial data according to the XML schema.

[c6] The method of claim 5 wherein the step of validating further comprises:
comparing entered data against a corresponding edit specification in the XML schema; and
receiving clinician input in response to a determination that the entered data does not conform to the corresponding edit specification.

[c7] The method of claim 6 wherein the step of receiving clinician input includes:
receiving corrected data that adheres to the corresponding edit specification.

[c8] The method of claim 6 wherein the step of receiving clinician input includes:
receiving validation annotation information recorded

with the entered data to explain the mis-comparison of the entered data relative to the corresponding edit specification.

[c9] The method of claim 6 wherein the step of receiving clinician input includes:
receiving validation status information recorded with the entered data to indicate the status of further investigation regarding the mis-comparison of the entered data relative to the corresponding edit specification.

[c10] The method of claim 1 wherein the step of storing includes:
employing a client certificate to secure the clinic trial data in the secure store of the remote computing system; and
associating the client certificate with the clinical trial data to secure the clinical trial data from unauthorized access.

[c11] A method of clinical trial data management comprising:
receiving clinical trial data from an examining clinician using a remote computer system;
determining whether the remote computer system is presently communicatively coupled to a central system;
forwarding the clinical trial data as XML messages to the central system in response to a determination that the

remote computer system is presently coupled to the central system;

spooling the clinical trial data on the remote computer system in response to a determination that the remote computer system is not presently coupled to the central system wherein spooling includes securing the clinical trial data on the remote computer system to preclude unauthorized access thereto; and

transmitting the spooled clinical trial data to the central system as XML messages in response to a subsequent determination that the remote computer system is again coupled to the central system.

[c12] A system for clinical trial data management comprising:

a remote computer system for use by an examining clinician wherein the remote computer system includes:

form data entry components for presenting a form to the clinician and for receiving clinical trial data as responses to the presented form;

hand drawn data entry components to receive digitized images of hand drawn information as clinical trial data;

a remote communication link for coupling the remote computer system to a central system; and

a remote secured store for temporary storage of the clinical trial data until transmission of the clinical trial data to the central system may be accomplished;

a central system for centralized storage, analysis and reporting of the clinical trial data wherein the central system includes:

a central communication link for coupling the central system to the remote computer system; and

a central secured store for storage of the clinical trial data received from the remote computer system; and

a communication medium coupled to the remote communication link and coupled to the central communication link for exchanging the clinical trial data between the remote computer system and the central system.

[c13] The system of claim 12 wherein the remote computer system comprises a hand held computing device.

[c14] The system of claim 13 wherein the hand held computing device comprises a tablet PC.

[c15] The system of claim 13 wherein the hand held computing device comprises a laptop computer.

[c16] The system of claim 12 wherein the remote computer system comprises a desktop computing device.

[c17] The system of claim 12 wherein the communication medium comprises a wireless communication medium.

[c18] The system of claim 12 wherein the clinical trial data

comprises XML messages.

[c19] A method in a computer system for managing clinical trial data entered by an examining clinician, comprising:
presenting to an examining clinician an electronic clinician data entry form defined as an XML schema on a remote display device of a remote computing system, said form having a set of data entry fields designed for receiving entry of a set of clinical trial data to be input by the examining clinician;
presenting to the examining clinician a prompt for selecting an option for manual entry of information; and
presenting to the examining clinician an indicator to begin manual entry of the digital information.

[c20] The method for managing clinical trial data as recited in claim 19 where presenting a prompt for selecting the option for manual entry further comprises presenting an option for manual entry utilizing a digital paper document scanner or manual entry utilizing an electronic digitizing tablet.

[c21] The method for managing clinical trial data as recited in claim 19, further comprising the steps of:
presenting to the examining clinician an invalid form data field entry indicator responsive to a validation processing computing component residing on the remote

computing system and operable to compare clinician entered data with a corresponding edit specification in the XML schema and presenting to the examining clinician a reentry prompt where the clinician can select to reenter corrected form data; and
presenting a reentry field responsive to a selection of reentry.

[c22] The method of claim 21, where presenting the reentry prompt further comprises presenting an optional annotation prompt in the alternative for entry of annotated entered data with entered explanation why the entry flagged as invalid is acceptable; and presenting an annotated reentry field responsive to a selection of annotated reentry.

[c23] The method for managing clinical trial data as recited in claim 19, further comprising the steps:
presenting to the examining clinician a submission prompt for selection to indicate that data entry is completed and submission is requested.

[c24] The method of claim 23, further comprising the steps of:
presenting to a requesting user a report prompt for selecting generation of a report of entered clinical trial data; and
presenting to the requesting user responsive to a selec-

tion of the report prompt, a report of the appropriate clinical trial data reformatted from the XML data according to the output requirements corresponding to the report prompt selected.

[c25] The method of claim 24, where the report is reformatted from the XML data in accordance with requirements of a select regulatory agency corresponding to the report prompt selected.

[c26] A system for clinical trial data management comprising:
a remote computer system for use by an examining clinician wherein the remote computer system includes:
form data entry components for presenting a form to the clinician and for receiving clinical trial data as responses to the presented form;
hand drawn data entry components to receive digitized images of hand drawn information as clinical trial data;
a remote communication link for coupling the remote computer system to a central system; and
a remote secured store for temporary storage of the clinical trial data until transmission of the clinical trial data to the central system may be accomplished.

[c27] The system of claim 26, where the hand drawn data entry component is operable to receive digitized hand drawn images from a paper document scanning device

communicably linked to the remote computer system and from an electronic digitizing tablet device communicably linked to the remote computer system.

[c28] The system of claim 26, where the remote computer system further comprises data entry validation components operable for validating data entered by the clinician by comparing entered data against a corresponding edit specification and for notifying the clinician when the data entry is invalid.

[c29] The system of claim 28, where the data entry validation component is further operable to prompt the clinician for reentry of corrected data and receive said corrected data and further operable to prompt the clinician to alternatively enter annotated data explaining why data need not be corrected and operable to receive said annotated data.

[c30] The system of claim 28, where the remote computer system further comprises:
a report selection component operable to receive a report selection from the clinician and further operable to initiate retrieval of the appropriate re-formatted XML clinical data responsive to and in accordance with the report selection.

[c31] The system of claim 30, where the remote computer system comprises a hand held computing device.

[c32] The system of claim 31 wherein the hand held computing device comprises a tablet PC.

[c33] The system of claim 31 wherein the hand held computing device comprises a laptop computer.

[c34] The system of claim 30 wherein the remote computer system comprises a desktop computing device.

[c35] The system of claim 26, further comprising:
a central system for centralized storage, analysis and reporting of the clinical trial data wherein the central system includes:
a central communication link for coupling the central system to the remote computer system;
a central secured store for storage of the clinical trial data received from the remote computer system; and
a communication medium coupled to the remote communication link and coupled to the central communication link for exchanging the clinical trial data between the remote computer system and the central system.

[c36] The system of claim 35 wherein the communication medium comprises a wireless communication medium.

[c37] The system of claim 35, where the central system further comprises:

a central data entry validation component operable to notify the remote computer system with a data invalidation error when data is determined to be invalid.

[c38] The system of claim 26, where the remote computer system further comprises:

a client certificate component operable to generate a client certificate to secure submitted data from unauthorized assets.

[c39] The system of claim 38, where the client certificate component is combined with a data encryption technique.